

REMARKS/ARGUMENTS

In this Amendment, claims 1-17 are currently amended. The amended claims are fully supported by the instant specification and prior claims. Thus, no new matter is introduced into the application by virtue of the amendments herein.

The amendments to the claims are clerical in nature and are presented to conform the claim language to standard U.S. practice and to correct grammatical oversights.

Accordingly, the presently pending claims in this application are claims 1-17.

Double patenting

Claims 1-17 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 9-27 of co-pending application U.S. Serial No. 10/507,344. The Examiner states that although the co-pending claims are not identical, they are not patentably distinct from each other.

To progress the prosecution of the instant application without acquiescing as to the merits of the rejection, Applicants submit herewith a terminal disclaimer and the required fee.

Accordingly, withdrawal of the provisional rejection under the judicially created doctrine of obviousness-type double patenting is respectfully requested.

The claims fulfill the requirements of 35 U.S.C. § 102

Claims 1-16 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Edgren et al. (U.S. Patent No. 4,503,030) (hereinafter "Edgren"). The Examiner characterizes Edgren's contemplated invention as "an oral osmotic device composed of a semipermeable material surrounding a compartment containing an active agent" The Examiner also states that Edgren's dosage form "contains an expression pathway that includes an aperture, orifice, bore, hole, or the like through the wall (col. 8, lines 25-30)." (09/13/2005 Office Action, page 3).

Applicants traverse the rejection.

It is well established that to anticipate under §102, each and every limitation of a claimed invention must be disclosed in a single reference. *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (Fed. Cir. 2000; *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001).

As recognized by the Examiner, Edgren's device is osmotic and is composed of a semipermeable membrane. *See, e.g.*, Edgren at Col. 5, lines 17-19 and lines 26-29, *et seq.* to Col. 6, lines 1-21. This stands in contrast with Applicants' presently claimed invention in which the described tablet is required to be completely coated with an insoluble and impermeable film coating. Unlike Applicants' presently claimed system, Edgren's device delivers drug by fluid being imbibed through the semipermeable wall into the interior compartment of the device housing a drug. (Col. 4, lines 25-27 of Edgren).

In addition, Edgren's osmotic device contains a hole or passageway in the wall through which drug is pumped. *See, e.g.*, Col. 3, lines 47-49; Col. 4, lines 25-25; and Col. 8, lines 25-30 of Edgren. In Edgren's device, prior to fluid contact, a hole is already formed through the membrane coating and is in communication with the core of the device. In distinction, Applicants' presently claimed tablet system involves a coating that completely and entirely surrounds the tablet core. The portion of the coating delimited by incision(s) is removed only after fluid contact.

In view of these distinctions as well as others, Applicants' therapeutic system is clearly different from and inapposite to that described by Edgren.

Because Edgren fails to disclose each and every element of Applicants' presently claimed invention, arranged as in the claim, this cited reference does not anticipate the present claims. Withdrawal of the §102(b) rejection in view of Edgren is thus respectfully requested.

Claims 1, 16 and 17 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Theeuwes et al. (U.S. Patent No. 4,088,864) (hereinafter "Theeuwes"). The Examiner states that Theeuwes "discloses a method of drilling a passageway into tables

(abstract)” and a tablet dosage form comprised of an active agent containing core that is surrounded by a semipermeable membrane. ...” The Examiner further mentions that Theeuwes discloses a CO₂ laser operated at a power range of 15-30 watts. (09/13/2005 Office Action, page 4).

Applicants disagree that the described method and tablet dosage form of Theeuwes anticipate the presently claimed invention.

Applicants’ presently claimed invention contains both structural and functional limitations that distinguish it from described tablet and method of Theeuwes. In particular, the wall of Theeuwes dosage form is comprised of a semipermeable material. *See, e.g.*, Col. 2, lines 48-50 of Theeuwes. In accordance with the invention contemplated by Theeuwes, the outer semipermeable material of the wall permits ingress of physiological media to start the osmotic process. *See, e.g.*, Col. 3, lines 3-13 of Theeuwes. This stands in contrast with Applicants’ presently claimed invention.

As taught by Theeuwes, the described method is designated for the pills containing a semipermeable-material containing wall, as disclosed by Theeuwes at Col. 2, lines 40-59. In contrast, Applicants’ present invention is drawn to a tablet and process of making same, in which the tablet film coating is both insoluble in and impermeable to aqueous fluid. The process described by Applicants is directed to making the therapeutic system comprising the tablet as described in Applicants’ claim 1. It is submitted that Applicants’ system is not an osmotic system with a dosage form having a semipermeable membrane as described by the cited reference.

Because Theeuwes fails to disclose each and every element of Applicants’ presently claimed invention, arranged as in the claim, this cited reference does not anticipate the present claims. Withdrawal of the §102(b) rejection in view of Theeuwes is thus respectfully requested.

Claims 1-17 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Faour (U.S. Patent No. 6,599,284) (hereinafter “Faour”). The Examiner states that Faour

discloses “a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), an intermediate layer forming a semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4). ...”

Applicants respectfully disagree that Faour anticipates the presently claimed invention.

Like both Edgren and Theeuwes, Faour relates to an osmotic device and system which has a semipermeable coating surrounding a core containing active ingredient(s). *See, e.g.*, Col. 4, lines 44-45; Col. 5, lines 3-5; Col. 5, lines 19-21; Col. 6, lines 57-59 and lines 66-67 to Col. 7, lines 1-2 and Col. 8, lines 22-23 of Faour. Faour’s osmotic device increases in size during use to deliver active agent. (*See*, Faour at Col. 1, lines 15-16; Col. 4, lines 6-11 and lines 24-28).

In contrast to the osmotic device described by Faour, Applicants’ presently claimed invention is directed to a tablet that comprises a film coating that is both insoluble in and impermeable to aqueous fluids. In further contrast to Faour, Applicants’ presently claimed invention does not involve initiation of an osmotic process by entry of physiological medium. Thus, Applicant’s invention as presently claimed is distinct and different from the device taught and disclosed by Faour.

Because Faour fails to disclose each and every element of Applicants’ presently claimed invention, arranged as in the claim, this cited reference does not anticipate the present claims. Withdrawal of the §102(e) rejection in view of Faour is thus respectfully requested.

The Examiner has indicated that U.S. Patent No. 4,160,020 to Ayer et al. and U.S. Patent No. 6,004,582 to Faour, of record, are considered pertinent to Applicants’ disclosure. Applicants submit that these references differ from the presently claimed invention for reasons similar to those set forth hereinabove and acknowledge the Examiner’s implicit recognition of the distinction of the claimed invention from the disclosures of these references that have been cited, but not relied on.

CONCLUSION

Applicants respectfully submit that the application is now in condition for allowance.
An action progressing this application to issue is courteously urged.

Should any additional fees be deemed to be properly assessable in this application for the timely consideration of this Amendment, or during the pendency of this application, the Commissioner is hereby authorized to charge any such additional fee(s), or to credit any overpayment, to Deposit Account No. **50-0311** (Reference No. **28069-603 NATL**).

Should a further Extension of Time be required in connection with the filing of this Amendment, the Commissioner is hereby requested to grant any such Extension of Time as may be deemed necessary, and is authorized to charge any such Extension of Time Fee as may be required to keep the application in good standing, to Deposit Account No. **50-0311** (Reference No. **28069-603 NATL**).

If the Examiner believes that further discussion of the application would be helpful, she is respectfully requested to telephone Applicants' undersigned representative at (212) 692-6742 and is assured of full cooperation in an effort to advance the prosecution of the instant application and claims to allowance.

Respectfully submitted,

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